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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,179	03/12/2004	Manoj Kumar	DOC0057PA/DC5074/GC792-4	8989

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DINSMORE & SHOHL LLP
One Dayton Centre
Suite 500
One South Main Street
Dayton, OH 45402-2023

EXAMINER

KOSAR, ANDREW D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,179

Applicant(s)

KUMAR ET AL.

Examiner

Andrew D Kosar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-33 are pending. Claims 1-33 require restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claim(s) 2, drawn to a personal care composition comprising a repeat amino acid sequence polymer derived from various proteins, such as dragline silk, wherein one embodiment is classified in class 514, subclass 21.

Group II, claim(s) 3-11, drawn to the composition of claim 1 comprising the sequence: $T_y[(A_n)_x(B)_b(A'_n)_x(A''_n)_x]_i T_y$, wherein one embodiment is classified in class 514, subclass 12.

Group III, claim(s) 15, drawn to the composition of claim 1 comprising SEQ ID NO:19, wherein one embodiment is classified in class 514, subclass 2.

Group IV, claim(s) 16-30, drawn to the composition of claim 1 which is a hair care, skin care, nail care, cosmetic, oral care, or over-the-counter pharmaceutical composition, classified in various classes and subclasses as set forth below:

Group IVa, claim(s) 17 and 24-26, drawn to the composition of claim 16 which is a hair care composition, classified in class 510, subclass 119 and class 424, subclass 70.2.

Group IVa(1), claim(s) 24 and 25, drawn to the composition of claim 17 which is a shampoo or conditioner, wherein one embodiment is classified in class 510, subclass 119.

Group IVa(2), claim(s) 26, drawn to the composition of claim 17 which is a chemical treatment, i.e.- dyes, relaxers, etc., wherein one embodiment is classified in class 424, subclass 70.2.

Group IVb, claim(s) 18, 19, and 27, drawn to the composition of claim 16 which is a skin care composition, wherein one embodiment is classified in class 424, subclass 70.9.

Group IVc, claim(s) 20, 21, and 28-30, drawn to the composition of claim 16 which is a cosmetic composition, classified in various classes and subclasses as set forth below:

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Group IVc(1), claim(s) 28, drawn to the composition of claim 21 which is mascara, wherein one embodiment is classified in class 424, subclass 70.7.

Group IVc(2), claim(s) 29, drawn to the composition of claim 21 which is pressed powder, wherein one embodiment is classified in class 424, subclass 69.

Group IVc(3), claim(s) 30, drawn to the composition is foundation, wherein one embodiment is classified in class 424, subclass 401.

Group IVd, claim(s) 22, drawn to the composition of claim 16 which is a nail care composition, wherein one embodiment is classified in class 424, subclass 401.

Group IVe, claim(s) 23, drawn to the composition of claim 16 which is an oral care composition, wherein one embodiment is classified in class 424, subclass 49.

Group V, claim(s) 32 and 33, drawn to a process of making a personal care composition, wherein one embodiment is classified in class 514, subclass 21.

Claims 12-14 and 31 are included in all groups I-IV.

Linking Claims

Claim 1 link(s) inventions I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1.

Claim 16 link(s) inventions IVa-IVe. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 16.

Claim 17 link(s) inventions IVa(1) and IVa(2). The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 17.

Claims 20 and 21 link(s) inventions IVc(1)-IVc(3). The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 20 and 21.

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Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I and II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the broad classification of compounds of compounds encompassed by the linking claim "repeat sequence protein polymer" defines three distinct generic species, wherein group I is defined conceptually as being derivatives of specific proteins, group II is defined as $T_y[(A_n)_x(B)_b(A'_n)_{x'}(A''_n)_{x''}]_i T_y$, and group III is defined as SEQ ID NO:19. The compounds of the different inventions are not disclosed as capable of use together and are structurally distinct one from another.

Inventions I-III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention IV is drawn to the broad generic "repeat sequence protein polymer", however the inventions of groups I-III have different modes of operation and different effects than those of group IV. Group IV is drawn to specific formulations of

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the generic claim 1, however it does not disclose the incorporation of any of the inventions of groups I-III as capable of use together.

Inventions IVa - IVe are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the compositions are drawn to different formulations (hair care, skin care, cosmetic, nail care, and oral care) with different functions, effects, and modes of operation.

Inventions IVa(1) and IVa(2) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the hair care compositions are drawn to two different functions, with different effects, and different modes of operation.

Inventions IVc(1) - IVc(3) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the compositions are not disclosed as capable of use together, have different functions and different effects. Mascara, pressed powder, and foundation each have different functions in beautification of the skin, and are intended to be applied to specific parts of the body, with a different desired effect for each.

Inventions I-IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

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process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, one could use the method to make compositions which are not personal care compositions, such as oral insulin. Further, as evidenced by the claims themselves, the personal care compositions made can be antifungal or sunscreens, for example. Additionally, the personal care compositions may be made by the process of liquid phase extraction of the active ingredient, a materially distinct process.

Election of Species

Claims 1-14 and 16-33 are generic to a plurality of disclosed patentably distinct species comprising "repeat sequence protein polymers". Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. A single disclosed species for group I identifies the compound particularly, and is supported by the specification. A single disclosed species for group II identifies and defines each variable (A, B, T, etc.), and is supported by the specification.

With regards to group II, the sequence range in amino acid residues is vast and encompasses a myriad of possibilities, wherein no substantial core was found among the variations possible, which would allow a coextensive search thereof. Thus, a separate and distinct search, as well as examination, of each sequence is required. Applicant is required, if group II is elected, to elect a single peptide sequence/SEQ ID NO: as the peptide of the invention. **This requirement for group II is not to be taken as an election of species, but rather an election of a single invention, since each**

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peptide is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Invention listed above is directed to, or involves the use or making of, compounds which are recognized in the art as being distinct from one another because of their diverse chemical structures (peptide sequences, etc.), their different chemical properties, modes of action, different effects, and reactive conditions (MPEP §§ 806.04 and 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over any of the other inventions, i.e.- they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of *Application of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and *In re Lalu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Additionally, the compounds present in the instant application are distinct, absent evidence to the contrary, and would require a unique search strategy. For example, the search for the distinct compounds of groups II and III is conducted based on their

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unique peptide sequences, while the search for inventions of groups I and IV would be conducted with text searching. Therefore, the search of one compound would not necessarily lead to the discovery of another compound, nor would it necessarily lead to the discovery of methods of using and/or making.

These inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search for one invention would not necessarily lead to the discovery of another invention. In addition, because of the plethora of combinations and distinct protein polymers in the Groups, a serious burden is imposed on the Examiner to perform a complete search of the defined areas. Therefore, because of the reasons given *supra*, the restriction set forth is proper and not to restrict would impose a serious burden in examination of this application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder Practice

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

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whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

NO CLAIMS ARE ALLOWED.

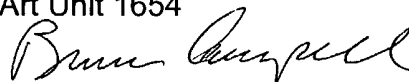
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew D. Kosar, Ph.D.
Patent Examiner
Art Unit 1654



BRUCE R. CAMPPELL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600